

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION**

TRUTEK CORP.,

Case No. 2:21-cv-10312

Plaintiff,

Hon. Stephen J. Murphy, III

v.

BLUEWILLOW BIOLOGICS, INC.,

Defendants.

**PLAINTIFF'S MOTION FOR LEAVE TO FILE AMENDED
COMPLAINT**

NOW COMES Plaintiff, Trutek Corp., by and through its counsel, Law Office of Stanley H. Kremen, Esq. and the Law Office of Keith Altman, and files its Motion for Leave to File Amended Complaint. For the reasons stated in the accompanying brief in support, Plaintiff respectfully requests that this Court GRANT the Motion.

Dated: May 11, 2022

Respectfully Submitted,



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PROCEDURAL HISTORY

Plaintiff, Trutek Corp. ("TRUTEK") filed this action on February 10, 2021. Defendant, BlueWillow Biologics, Inc. ("BLUEWILLOW") filed an answer with counterclaims on May 19, 2021. Prior to that time, the Parties engaged in talks aimed at resolving the dispute. Those discussions were unsuccessful. On November 3, 2021, the Court ordered a Fed. R. Civ. P. 16/26 conference. On that same date, the Court entered a Scheduling Order (ECF No. 21). That Order established various discovery deadlines. On March 23, 2022, the Court issued an Amended Order (ECF No. 26), wherein the discovery deadlines were extended by forty-five days. It was further ordered that the Parties must mediate no later than July 22, 2022.

The Court appointed Thomas M. Schehr, of Dykema Gossett PLLC, as mediator of the dispute. An initial telephonic conference was held between the mediator and counsel for both parties. Mr. Schehr was made aware of the issues as well as the fact that discovery was ongoing. It was decided that a subsequent mediation session will be held on June 6, 2022 via ZOOM.

LEGAL STANDARD

Fed. R. Civ. P. 15(a)(2) provides that courts should "freely give leave" to the moving party to amend the complaint "when justice so requires." In deciding whether to grant such relief, courts must consider "the delay in filing, the lack of notice to the opposing party, bad faith by the moving party, repeated failure to cure deficiencies by previous amendments, undue prejudice to the opposing party, and futility of amendment." *Perkins v. American Elec. Power Fuel Supply, Inc.*, 246 F.3d 593, 605 (6th Cir. 2001). "A proposed amendment is futile if the amendment could not withstand a Rule 12(b)(6) motion to dismiss." *Rose v. Hartford Underwriters Ins. Co.*, 203 F.3d 417, 420 (6th Cir. 2000) (citing *Thiokol Corp. v. Dep't of Treasury, State of Michigan, Revenue Div.*, 987 F.2d 376, 382 (6th Cir. 1993)). When the moving party has delayed seeking an amendment to the complaint, the purported reason for the delay must be balanced against any prejudice resulting to the opposing party. *Johnson v. Ventra Group, Inc.*, 124 F.3d 197 (6th Cir. 1997) (citing *Head v. Timken Roller Bearing Co.*, 486 F.2d 870, 873 (6th Cir. 1973)).

ARGUMENT

I. Plaintiff is Entitled to Amend Its Complaint to Add and Remove Counts of the Complaint and to Add and Remove Parties.

Per the *Perkins* court, four factors are considered in determining whether this motion should be granted: "the delay in filing, the lack of notice to the opposing party, bad faith by the moving party, repeated failure to cure deficiencies by previous amendments, undue prejudice to the opposing party, and futility of amendment."

a. There Was No Undue Delay in Filing the Proposed Amended Complaint.

Discovery is ongoing, and more information is available now that could not have been and in fact was not available to TRUTEK before the filing of this motion. The initial complaint alleged a single count of infringement of TRUTEK's U.S. Patent No. 8,163,802 (the '802 Patent) by BLUEWILLOW. BLUEWILLOW manufactured and sold a product labeled Nanobio® Protect, which TRUTEK alleges infringes claims 1, 2, 6, and 7 of the '802 Patent. This product is no longer being sold. (See ¶7 of decl. Kremen (attached hereto as Exhibit A).) At some time, subsequent to filing the initial complaint, TRUTEK

discovered that BLUEWILLOW's main activities are directed to developing nasally administered vaccines to prevent and/or treat various diseases and conditions. (Decl. Kremen ¶18.) During numerous discussions, BLUEWILLOW counsel asserted that the vaccines were "off-limits" because they were protected from infringement allegations according to Hatch Waxman. (Decl. Kremen ¶19) BLUEWILLOW counsel indicated that they would resist TRUTEK's efforts to discover information regarding the vaccines. (Decl. Kremen ¶19.) Consequently, TRUTEK began its own research. TRUTEK engaged experts to assist in its research. (See decl. Lemmo – attached hereto as Exhibit B.) At the present time, TRUTEK has a good faith belief that BLUEWILLOW's vaccine products read on at least claims 1 and 2 of the '802 Patent, and that BLUEWILLOW's activities infringe the '802 Patent.

The safe harbor provided by Hatch Waxman is an affirmative defense, and as such, BLUEWILLOW bears the burden of proof. In addition, not all activities of a producer of pharmaceuticals prior to regulatory approval are protected by the safe harbor. Further, TRUTEK has become aware that other entities are likely collaborating with BLUEWILLOW in their efforts to produce its vaccines. At least one of these entities is believed to be based outside the United States. Activities of these entities may not be encompassed by the safe harbor.

Discovery is required. A subsequent amendment of the complaint may be required to add these entities as their activities with respect to Defendant's vaccine development are discovered.

Moreover, even if some of BLUEWILLOW's activities are protected by the safe harbor during development, BLUEWILLOW should not be permitted to commercialize these products until expiration of the '802 Patent. Almost immediately following regulatory approval of their vaccines, BLUEWILLOW is expected to begin marketing them. At that time, not only will their activities constitute patent infringement, but they will further constitute willful infringement necessitating additional penalties.

Trying this case without citing infringement by BLUEWILLOW with respect to its vaccine development would make little sense. These activities are performed by the same defendant, and they infringe the same claims of the '802 Patent. Considering BLUEWILLOW's stated intent to resist discovery regarding its vaccine development, the additional count of infringement provides a rational basis for this avenue of discovery.

From the viewpoint of judicial economy, it makes sense to grant this motion to file an amended complaint because a separate action filed against the

same defendant for infringement of the same patent due to different activities would be redundant in terms of witness testimony. Allowing TRUTEK to file its amended complaint would allow this action to encompass the entire controversy between the parties.

b. The Lack of Notice to the Opposing Party.

Since before the Rule 16/26 scheduling conference, Defendants have been on notice that TRUTEK intends to pursue discovery into BLUEWILLOW's activities regarding its vaccine development. At the initial teleconference with the court appointed mediator, counsel for both parties voiced disagreement regarding the scope of the lawsuit. In a telephonic meet-and-confer session between counsel, BLUEWILLOW was placed on notice that TRUTEK intends to file this amended complaint. Counsel for BLUEWILLOW stated that Defendant would oppose Plaintiff's motion to amend.

c. Bad Faith by the Moving Party.

A simple review of the filings and the discovery that has taken place thus far demonstrates that there is no bad faith here by the Plaintiff. TRUTEK could not allege its new count of infringement until it had a good faith belief that it

was true. TRUTEK expended significant expense and labor to arrive at this belief. Plaintiff believes that it is unlikely for there to be any alleged bad faith in response. Should bad faith be raised in Response to this Motion, Plaintiff will reply accordingly.

d. Repeated Failure to Cure Deficiencies by Previous Amendments.

The proposed amended complaint represents Plaintiff's first amendment. There are no previous amendments. However, despite repeated opposition by Plaintiff, Defendant's counsel stated repeatedly that it intended to limit the scope of the present lawsuit to BLUEWILLOW's activities with respect to the Nanobio® Protect product. The proposed amended complaint simply explains and clarifies what exactly at the heart of this litigation. TRUTEK simply desires to protect its '802 Patent. The causes of action are clear as how BLUEWILLOW is alleged to have committed each violation.

e. Undue Prejudice to the Opposing Party.

As explained herein, Plaintiff believes it is unlikely that Defendant will even claim prejudice. Discovery has commenced recently. Interrogatories were served by both parties, requests for admission were served by Plaintiff, and

requests for production were served by Defendant. No depositions have been taken to-date. Defendant was aware that for several months, Plaintiff sought to serve discovery regarding Defendant's vaccine development activities. The proposed amended complaint formalizes the reasons for this discovery.

f. Futility of Amendment.

A mere cursory review of the proposed amended complaint reveals that it would survive a 12(b)(6) motion. The facts are pleaded with sufficient particularity that Plaintiff has stated a claim for each count. The proposed amended complaint stands on its own despite the affirmative defense of non-infringement, the Hatch Waxman safe harbor defense, and the counterclaim of patent invalidity. For these, the burden of proof rests with Defendant.

CONCLUSION

In view of the foregoing, Plaintiff respectfully requests that the Court grant its motion to amend the complaint.

Dated: May 11, 2022

Respectfully Submitted,



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CERTIFICATE OF SERVICE

I certify that on May 11, 2022, I served the foregoing Plaintiff's Motion for Leave to File Amended Complaint and Plaintiff's Brief in Support of Plaintiff's Motion for Leave to File Amended Complaint upon all parties herein by filing copies of same using the ECF System.



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